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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/614,105	07/08/2003	Isao Yamazaki	KAS-187	7653
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EXAMINER				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/614,105

Applicant(s)

YAMAZAKI ET AL.

Examiner

NEIL TURK

Art Unit

1797

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 March 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 7/8/03 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/CD/CD)
Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Remarks

This Office Action fully acknowledges Applicant's remarks filed on December 9th, 2008 and March 9th, 2009. Claims 13-18 are pending. Claims 1-12 have been cancelled.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 9th, 2008 has been entered.

Examiner notes the early, improvidently issued Office Action dated February 10th, 2009, and the Action provided below takes the current claim set and arguments into account, as well as those presented on 12/9/08.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the *analyzer* of the claims must be shown or the feature(s) canceled from the claim(s). No new matter

should be entered. Examiner notes that Applicant's drawings show a detector 51, but there are is no labeled element in the drawing which is denoted as the analyzer in the specification.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 13-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The recitation in claim 13 which recites, "...an analyzer arranged to analyze reactions involving reagents and analysis items taking place in said reaction cells..." constitutes new matter in the claims. Applicant's specification describes an automatic analyzer, in which the automatic analyzer is presented as the overall system. Applicant's disclosure does not provide basis for an analyzer arranged to analyze reactions involving reagents and analysis items taking place in said reaction cells. Examiner asserts that, however, Applicant's specification provides basis for a light source 50 and optical detector 51 for performing optical measurements within the reaction cells (see paragraphs [0025,0031], figs 1&2, for example, of the pre-grant publication US 2004/0105783). Applicant's disclosure further provides that there is a controller 60 which receives the results of the optical measurements performed by the detection unit 51, and the controller functions to calculate the concentration of the measurement items. Examiner thereby asserts that Applicant's disclosure provides basis for an "analyzer" in the sense of a light source 50 and detector 51 arranged correspondingly about the reaction disk and in constitution with the additional functionality to the controller 60 to receive the optical results from the source/detector so as to calculate the concentration of the measurement items.

Claims 16-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The recitation in claims 16-18 which recites, "...further comprising a package in each of said plurality of reagent containers..." constitutes new matter in the claims. From Applicant's specification, that the package is not a positive element of the device. Applicant's pre-grant publication (US 2004/0105783) in paragraph [0017] recites that the reagent containers *may be constructed such that* it can store in a single package both of a first reagent and a second reagent. Examiner further notes that original claim 12 recites, "...reagent containers can each store in a single package both of a first reagent and a second reagent..." These disclosures are related to the configuration of the reagent container and its holding capabilities, and do not provide basis for the packages being positive elements of the device, as currently claimed in claims 16-18.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 13-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear how an analyzer is arranged to analyze reactions involving reagents and analysis items taking place in said reaction cells such

that no analysis items have been positively recited and provided to the reaction cell so as to allow such reactions to occur (for analysis thereof). Do each of the reaction cells on the reaction disk contain an analysis item therein? Further, what is meant by an analysis item? Is this a sample, such as blood, to which the reagents are added for reaction and subsequent analysis?

It is further unclear how "the controller controls the operations of said first and second reagent dispensing probe so that a single analysis item is analyzed by using reagents in reagent containers arranged on the same reagent disk", as recited in claim 13, such that an analysis (or a plurality thereof as implied by the control function herein recited) item has not been positively and definitely established in the claims. How is the analysis item defined in the device? Is the analysis item an individual sample provided to a reaction cell? Clarification is required.

Claim 13 recites the limitation "said reaction disks" in. There is insufficient antecedent basis for this limitation in the claim.

Claims 16-18 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The recitation to the reagent containers storing the first and second reagents in a package is unclearly recited. From Applicant's specification, it appears that the package is not a positive element of the device. Applicant's pre-grant publication (US 2004/0105783) in paragraph [0017] recites that the

reagent containers may be constructed such that it can store in a single package both of a first reagent and a second reagent. This disclosure is related to the configuration of the reagent container. Applicant should amend the claims to recite that the reagent containers are constructed to allow a package to be contained therein which has both the first and second reagent. As such, prior art which discloses reagent containers that are capable of holding a package with first and second reagent will be said to read on the limitations of claims 16-18.

Claims 16-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear how first and second reagent is taken from the packages as necessary for the operation of the dispensing probes and thereby the analysis by the analyzer. What structure is provided for piercing or gaining access to the reagents that are packaged? Does Applicant intend to claim a piercing structure attached to the dispensing probes for accessing the reagents therein. Further, claims 16-18 are unclear in how each of the dispensing probes relates to the first and second reagents stored in each package. Claim 13 recites that a first reagent dispensing probe is arranged to dispense the first reagent and a second reagent dispensing probe is arranged to dispense a second reagent. Now that claims 16-18 provide both first and second reagents in a single package, it is unclear how the first and second dispensing probes may function to selectively suck the first or second reagent as recited. Clarification is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 13, 14, 16, and 17 are rejected under 35 U.S.C. 103(a) as obvious over Ohishi et al. (6,019,945), hereafter Ohishi, in view of Ginsberg et al. (4,234,538), hereafter Ginsberg.

Ohishi discloses a sample analysis system. Ohishi shows in figure 3 a controlled (connected to computer 6B and control unit 40; computer 6A as designated in fig. 2)

analysis unit 3B in which there are a plurality of reagent disks 26a, 26b. Ohishi also shows a plurality of reagent dispensing probes 8a, 8b arranged to suck reagent from one of the reagent containers (12a, 12b; which are capable of holding first and second reagents in a package), and inject the reagent into one of the reaction cells 46b (within reactor section 5b). Examiner further asserts that the reagent dispensing probes 8A, 8B are controlled so that only one of the first and second reagent dispensing probes sucks/injects first or second reagent during a predetermined cycle of a pitch and a stop of said reaction disk. This is such that one of the plurality of reactor cells 46B, which has been preloaded with sample (analysis item), is brought to a stop at a first position at which reagent pipetter 8A is controlled to inject first reagent into reactor cell 46b, while the second dispensing probe is uncontrolled and does not dispense second reagent at such a pitch and stop of the reactor cell. Ohishi discloses that the reactor cell is then moved to arrive at a second position where pipetter 8B is controlled to inject the second reagent to the reactor cell 46, while the first pipetter is idle (lines 23-67, col. 6; lines 1-13, col. 7, fig. 3). Ohishi discloses light source 14a and multi-wavelength photometer 15a for optical measurement of the reactor solution in reactor cells 46b; Ohishi further discloses that the signal from photometer 15a is converted by A/D converter 30A and distributed over computer 6A to host control computer 40 (lines 1-23, col. 6).

Ohishi does not disclose including first and second reagent dispensing probes arranged at each of the reagent disks. Ohishi also does not disclose that the controller controls the operations of said first and second reagent dispensing probes so that a

single analysis item is analyzed by using reagents in reagent containers arranged on the same reagent disk.

Ginsberg discloses an automatic analyzer that includes first and second reagent dispensers 44, 46 arranged about a reagent disc 42, such that first and second reagent are added from the same reagent disk to a reaction cuvette 32 (analysis item; analyzed by light source 50/detector 52) (abstract; lines 20-32, col. 5, fig. 1).

It would have been obvious to modify Ohishi to include first and second reagent dispensing probes arranged at a disk, and further to control the first and second reagent dispensing probes so that a single analysis item is analyzed by using reagents in reagent containers arranged on the same reagent disk such as taught by Ginsberg in order to provide a second available, and clean dispensing probe that is available for immediate use on the next progression, and further providing both necessary reagents on a single reagent disk as taught by Ginsberg as an alternative arrangement of the necessary first and second reagents, which provides a single reagent disk for carrying out the necessary reaction, so that throughput is not decreased by breakdown of the other reagent disk. Further, it would be obvious to apply this to both reagent disks of Ohishi (26A and 26B) so that a second, clean dispensing probe would be available to both of the first and second reagents contained at the reagent disks 26A, 26B; thereby throughput would increase as fewer cleaning steps for the dispensing probes would be required and more probes would be available to dispense reagent into the reaction containers within the reaction disk.

Claims 15 and 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ohishi in view of Ohishi in view of Ginsberg as applied to claims 13,14, 16, and 17 and in further view of Minekane (4,808,380).

Ohishi/Ginsberg does not disclose at least one reagent disk arranged inside a reaction disk.

Minekane discloses an automatic chemical analyzing apparatus. Minekane discloses a cuvette rotor 18 in which cuvettes 20 are mounted in an annular array to receive sample and reagent to be then analyzed by a photometer (reaction disk 18 with reaction cells 20). Minekane further discloses reagent supply 14, which has a pair of coaxial reagent rings 24 and 26, and is placed peripherally within the ring of cuvette arrays (arranged inside the reaction disk) (lines 19-67, col. 2, fig. 1).

It would have been obvious to modify Ohishi /Ginsberg to arrange reagent disks inside the reaction disk such as taught by Minekane in order to save space and optimize the workspace area.

Response to Arguments

Applicant's arguments with respect to claim 1-12 have been considered but are moot in view of the new ground(s) of rejection. As claims 1-12 have been cancelled, such arguments are moot, and claims 13-18 have been rejected as discussed above. The drawings are objected to as not showing the analyzer of claims 13-18. Claims 13-18 are rejected under 35 USC 112, 1st paragraph and 2nd paragraph, as discussed above. Claims 13, 14, 16, and 17 are rejected under 35 USC 103(a) over Ohishi in view

of Ginsberg, and claims 15 and 18 are rejected under 35 USC 103(a) over Ohishi in view of Ginsberg and in further view of Minekane.

Applicant argues that the Ohishi in view of Ginsberg does not disclose "only one of the first and second reagent dispensing probes for each of said reagent disks sucks said first or second reagent...during a predetermined cycle." Examiner argues that Ohishi in view of Ginsberg does disclose such a recitation. Examiner asserts that the reagent dispensing probes 8A, 8B are controlled so that only one of the first and second reagent dispensing probes sucks/injects first or second reagent during a predetermined cycle of a pitch and a stop of said reaction disk. This is such that one of the plurality of reactor cells 46B, which has been preloaded with sample (analysis item), is brought to a stop at a first position at which reagent pipetter 8A is controlled to inject first reagent into reactor cell 46b, while the second dispensing probe is uncontrolled and does not dispense second reagent at such a pitch and stop of the reactor cell (lines 23-67, col. 6, for example).

Further, as discussed above, the combination of Ohishi with Ginsberg provides to remedy the deficiencies of Ohishi and presents an obvious combination over the claims.

With regards to claim 15, Examiner argues that the combination of Ohishi in view of Ginsberg and in further view of Minekane reads on the claim limitations. Minekane discloses a reaction disk 18 with reaction cells 20 and reagent disk, such as disk 24 arranged inside of the reaction disk. Thereby, the combination as discussed above, meets the recitation to a reagent disk being arranged inside a reaction disk. Examiner

asserts that Minekane thereby shows that arrangement of a reagent disk inside a reaction disk provides to save space, thus optimizing the workspace.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NEIL TURK whose telephone number is (571)272-8914. The examiner can normally be reached on M-F, 9-630.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NT

/Jill Warden/
Supervisory Patent Examiner, Art Unit 1797